K091195

MAY 27 2009

510(k) Summary
Philips Medical Systems (Cleveland) Inc.
"Brilliance Volume"

This summary of this 510(k) provides safety and effectiveness information submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter

Philips Medical Systems (Cleveland), Inc.
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(440) 483-3000

Contact:

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Date of Summary: February 25, 2009

2. Device Name and Classification

Device Name: MX 16-slice CT System, phase II
Classification Name: Computed Tomography X-Ray System

The FDA has classified the Computed Tomography X-Ray System and its accessories as Class II in 21 CFR 892.1750 (Product Code 90 JAK)

3. Predicate Device Information

In the opinion of Philips Medical Systems Inc., the MX 16-slice CT System, phase II is of comparable type and substantially equivalent to the legally marketed devices currently in commercial distribution, namely: the Brilliance CT 16-slice in K012009 (a.k.a. MX8000 IDT CT Scanner). It expands the capabilities of the MX 16-slice CT system (K083498).

4. Device Description

The MX 16-slice CT System, phase II is a Whole Body Computed Tomography X-Ray System featuring a continuously rotating X-ray tube and detectors gantry and multi-slice capability. The acquired x-ray transmission data is reconstructed by computer into cross-sectional images of the body taken at different angles and planes. This device also includes signal analysis and display equipment, patient and equipment supports, components and accessories.

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5. Intended Use of the device

The MX 16-slice CT system can be used as a Whole Body Computed Tomography X-ray System featuring a continuously rotating x-ray tube and detector array with multislice capability up to 16 slices simultaneously. The acquired x-ray transmission data is reconstructed by computer into cross-sectional images of the body from the same axial plane taken at different angles. The system is suitable for all patients.

6. Comparison to Predicate Devices

In the opinion of Philips Medical Systems (Cleveland), Inc., the "Philips MX 16-slice" CT scanner is of comparable type and substantially equivalent to the legally marketed devices because it has the similar technological characteristics and sub-assemblies as the current commercial distribution of Brilliance CT 16-slice (K012009).

The safety and effectiveness of the "Philips MX 16-slice" is assured by adherence to Good Manufacturing Practices (GMP) 21 CFR 820 and to International Standards ISO 13485:2003. Potential hazards are identified in a hazard analysis and controlled in the following manner:

Software safety is assured by the company procedures that conform to accepted practices. Quality assurance procedures are adhered to, and meeting the specifications and functional requirements is demonstrated via testing.

Electrical and Mechanical safety is assured by adherence to IEC 60601-1 Standards.

Radiation safety is assured by compliance with 21 CFR, Subchapter J Performance Standards.

Based on the above considerations, it is Philips's opinion that the **MX 16-slice CT Scanner** is substantially equivalent in safety and effectiveness to the predicate device: Brilliance CT 16-slice with 510(k) Number K012009.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2009

Philips Medical Systems (Cleveland), Inc.
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K091195
Trade/Device Name: Philips MX 16-slice CT system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 8, 2009
Received: May 12, 2009

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

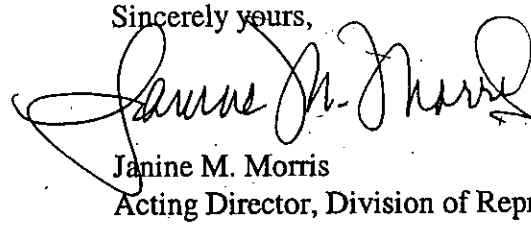
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Device Name: **Philips MX 16-slice CT system**

Indications for Use:

The Philips MX 16-slice CT system can be used as a Head and Whole Body Computed Tomography X-ray System featuring a continuously rotating x-ray tube and detector array with multislice capability up to 16 slices simultaneously. The acquired x-ray transmission data is reconstructed by computer into cross-sectional images of the body from the same axial plane taken at different angles. The system is suitable for all patients.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091195